DEC 18 2013

JEIL MEDICAL CORPORATION
#702, Kolon Science Valley 2nd, 811
Guro-Dong, Guro-Gu, Seoul, 152-050 Korea
Tel : +82 2 850 3500 / Fax : +82 2 850 3535

510(k) Summary

[As required by 21 CRF 807.92]

1. Date Prepared [21 CRF 807.92(a)(a)]

10 September 2013

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: Jeil Medical Corporation
  - Address: #702, Kolon Science Valley 2nd
811, Guro-dong, Guro-gu
Seoul, 152-050, Korea
- Contact Name: Hyeroung LEE (Ms.) / RA Manager
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  - Email Address : carine@jeilmed.co.kr
- Registration Number: 3004049923
- Name of Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name: ARIX Hand Locking System
- Common Name: Bone plates and screws
- Classification Name: Single/multiple component metallic bone fixation appliances and accessories
- Classification Panel: Orthopedic
- Classification Regulation: 21 CFR 888.3030

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- Product Code: HRS
- Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow;

- 510(k) Number: K062498
- Applicant: Howmedica Osteonics Corp.
- Common Name: Bone plates and screws
- Device Name: Profyle® System

- 510(k) Number: K023360
- Applicant: Jeil Medical Corpoation
- Common Name: Bone plates and screws
- Device Name: Leforte System Bone Plate

- 510(k) Number: K023365
- Applicant: Jeil Medical Corpoation
- Common Name: Bone plates and screws
- Device Name: Leforte System Bone Screw

There are no significant differences between the Model ARIX Hand Locking System and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, and operational principles as internal fixation components.

5. Description of the Device [21 CFR 807.92(a)(4)]

The ARIX Hand Locking System is rigid fixation consisting of plates and screws in various configurations, shapes and sizes as follow;

	Plate	**Cortical Screw**	**Locking Screw**
Type / Configuration	F2L-Series	20-HF-Sereis	20L-HF-Series
Material	ASTM F 67 Pure Titanium	ASTM F 136 Titanium Alloy (Ti-6Al-4V)	ASTM F 136 Titanium Alloy (Ti-6Al-4V)

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The ARIX Hand Locking System is made of Pure Titanium and Titanium Alloy (Ti-6AL-4V), which meet ASTM F67, Standard Specification for Unalloyed Titanium for Surgical Implant Applications, and ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, which are widely used for surgical implants with well-known biocompatibility. The plates vary essentially through different lengths and number of plate holes. The cortical screws & locking screws diameter is 2.0mm and lengths is from 6mm to 30mm. It also includes various manual surgical instruments, as drill guides, drill bits, driver shafts, depth gauge, bender and handbody. The ARIX Hand Locking System is not provided sterile. It is required to be sterilized via autoclave method to reach a SAL of 10^{-6} by the hospital prior to surgery.

This device performance is not adversely affected by aging or storage conditions since this device is to be sterilized at the hospital before use and also to be single use.

6. Intended Use [21 CFR 807.92(a)(5)]

The ARIX Hand Locking System is intended for use in internal fixation of the bones of hand and wrist. Examples of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and the treatment of fractures.

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7. Technological Characteristics [21 CFR 807.92(a)(6)]

ARIX Hand Locking System, Bone Plates: Based on a technical feature comparison, the subject device was found to be similar to all predicate devices with regard to design and materials. The subject plates also have a polyxial locking feature, similar to the design used in the predicate devices (K062498, K023360).

ARIX Hand Locking System, Bone Screws: They share similar head, neck and thread designs as the smaller screws that are currently cleared under the predicate devices (K062498, K023365).

Non-Clinical Test Summary:

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ASTM F 382-99, Standard Specification and Test Method for Metallic Bone Plates
- ASTM F 543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws

The following tests were performed with the predicate devices:

- Plates
  - Dimension test
  - Tensile strength test
  - Bending strength test per ASTM F382
- Screws
  - Dimension test
  - Driving torque test per ASTM F543-07
  - Axial pull-out test per ASTM F543-07
  - Torsion test per ASTM F543-07

The results of this testing indicate that the ARIX Hand Locking System is equivalent to predicate devices.

Clinical Test Summary:

No clinical studies were considered necessary and performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2013

Jeil Medical Corporation
Ms. Hyeroung Lee
Regulatory Affairs Manager
#702, Kolon Science Valley 2nd
811, Guro-dong, Guro-gu
Seoul 152-050
Republic of Korea

Re: K132876
Trade/Device Name: ARIX Hand Locking System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: September 24, 2013
Received: September 25, 2013

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K132876

Device Name: ARIX Hand Locking System

Indication for Use:

The ARIX Hand Locking System is intended for use in internal fixation of the bones of hand and wrist. Examples of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and the treatment of fractures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices